REMARKS/ARGUMENTS

As a result of the foregoing amendment, the specification has been revised to correct the priority paragraph in accordance with the Examiner's suggestion. Additionally, the numerous superscripts referred to by the Examiner have been deleted. It is noted, however, that the superscripts referred to the numbers of thereferences which were submitted as an addendum with the original provisional application Serial Number 60/480, 206, from which the present application claims priority. Applicant submits herewith an Information Disclosure Statement listing these references.

With respect to Table 9 on page 14, the two right-hand columns represent two separate experiments carried out using the technique described in paragraph [00040] and the table in this paragraph has been amended or to show that these are the results from each one or of these experiments.

The various typographical errors in the claims referred to in paragraphs 4-6 have also been corrected by virtue of the amendment to the claims. Accordingly, it is submitted that all of the objection was raised in paragraphs number 2-6 have been obviated by this amendment and these objections should be withdrawn.

Reconsideration and withdrawal of the rejection of claims 1-14 under the 1st paragraph of 35 USC 112 as failing to comply with the enablement requirement are requested. The Examiner asserts that the subject matter is not described in this specification in such a way as to enable one skilled in this art to which it pertains, or with which it is most nearly connected, to make and/or use

the invention. However, it is submitted that this conclusion is incorrect in light of a careful reading of the specification and drawings as presented.

Firstly, the Examiner asserts that the Ostrow *et al*. reference found that rabbits treated with CTC-96 displayed a dose-dependent increase in tumor size, time to first tumor, a number of rabbits developing tumor referring to Table 1 and that Ostrow *et al*. showed that the use of CTC-96 may be contraindicated in patients with papilloma virus. However, this work was done on cottontail rabbit papilloma. The cottontail papilloma virus is a poor paradigm for human papilloma viruses and was used by Ostrow *et al.* because it is easier to handle than either human or bovine papilloma viruses. HPV 11 (*in vivo*) and bovine papilloma virus (*in vitro*) are the acceptable models for the disease. Clearly, inasmuch as Ostrow *et al*. provided results and stated opinions based on a different papilloma virus from that described in use in the present application, the conclusion quoted by the Examiner stated with respect to the results is not relevant to the findings of the present inventor and the efficacy and usefulness of the invention as claimed. As is clear from the present specification, HPV 11 and bovine papilloma virus were used in the experiments depicted. Consequently, the description and results and conclusions of Ostrow *et al*. are not relevant to the present invention as claimed. To the extent that the Examiner believes that the art suggest that CTC-96 is not effective to treat papilloma virus, it is manifest that the presently claimed invention and findings depicted and described in the present application fly in the face of this prior art description and conclusion.

The Examiner concedes that the results disclosed in tables 9 to 11 demonstrate that the treatment of C127 mouse epithelial cells *in vitro* with CTC-96 effectively inhibits bovine papilloma virus from transforming said cells. The Examiner further asserts that while the *in vitro* data is convincing, the data is not given as much weight as *in vivo* data.

In paragraph 9g, the Examiner asserts that the standard deviation is large for all groups tested. However, with respect to the graft size, the median values as depicted in Table 5 were disregarded by the Examiner. The Examiner used only the means without the standard deviation which is reflected in the median values.

It should be further noted that the Examiner claims that no *in vivo* determination of papilloma virus were disclosed as set forth in paragraphs 2 g and h of the office action. However, Tables number 3, 4, 6, and 7 are all human papilloma virus determinations in grafts that are in skin and *in vivo*. Human foreskin was grafted onto the skin of SCID mice because the human virus (HPV 11) cannot proliferate in mouse tissue. Attached hereto is a figure (labeled Exhibit A) which shows the effectiveness of CTC 96 on graft size. This figure will be submitted with a declaration by the inventor. This figure shows the effectiveness of that CTC 96 on graft size. The results show a dramatic and distinct statistically significant microbicidal effect of CTC 96 (Doxovir™). The graft size in the control group was significantly larger than that in the three CTC 96 concentration groups. Furthermore, concentrations of 0.2% and 1.0% of CTC

96 were equally effective. The data in this submitted figure is similar to that shown in figure 2 of the application as filed.

It is noted that figures 1 and 2 were submitted with provisional application serial number 60/480206, from which the present application claims priority. A copy of the provisional application is forwarded herewith. Accordingly, the rejection under the 1st paragraph of 35 USC 112 is improper and should be withdrawn.

Referring to the Examiner's rejection under the 2nd paragraph of 35 USC 112, it is submitted that the present application makes clear what the metes and bounds of the recitation referring to an administration of an anti-papilloma virus disease effective amount of CTC-96 is. The specification points out in paragraph [0006] that the compound may be administered in the form of an aqueous solution but also by other conventional routes. In addition, in paragraph [0002] the invention is depicted in terms of the discovery that the drug CTC-96 may be administered to the subject infected with or who is susceptible of being infected with papilloma virus to alleviate the degree of infection or decrease the likelihood that the subject will be infected with papilloma virus. It is clearly within the skill of the artistan and, understanding the purpose of the administration and the desired result to modify the administration to achieve the desired result with any particular patient. Clearly, the metes and bounds of the invention as claimed is to administer a sufficiently effective amount of the drug to achieve the desired result. This rejection should also be withdrawn.

Accordingly, it is submitted that this application is in condition for allowance, and favorable reconsideration and prompt notice to that effect are earnestly solicited.

Respectfully Submitted,

August 31, 2009
Date

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